IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS GALVESTON DIVISION

ESTELA MEJIA and ELVIN MEJIA,	§	
Individually and as Heirs at Law of the	§	
Estate of Lizbeth Mejia,	§	
	§	
Plaintiffs,	§	
	§	CIVIL ACTION NO. 3:22-cv-159
v •	§	
	§	
ABBOTT LABORATORIES, INC.,	§	
MEAD JOHNSON & COMPANY,	§	
LLC, and	§	
MEAD JOHNSON NUTRITION	§	
COMPANY,	§	
	§	
Defendants	§	

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE UNITED STATES DISTRICT JUDGE

Estela Mejia and Elvin Mejia (collectively "Plaintiffs"), Individually and as Heirs at Law of the Estate of Lizbeth Mejia, hereby file this Original Complaint by and through their undersigned counsel against Defendant Abbott Laboratories, Inc., Defendant Mead Johnson & Company, LLC, and Defendant Mead Johnson Nutrition Company (collectively "Defendants"). For cause of action, Plaintiffs show the Court as follows:

I. NATURE OF THE ACTION. PARTIES, AND SERVICE OF CITATION

1.1 Enabled Texas Civil Practice & Remedies Code §§ 71.002 and 71.021, Plaintiffs bring this wrongful death and survival action as a result of the May 18, 2020 death of Lizbeth Mejia – <u>a five (5) day old infant.</u> Lizbeth Mejia's untimely death was proximately caused by Defendants' wrongful conduct in connection with the design, development, manufacture,

testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Similac cow-based formulas and Enfamil cow-based formulas, including but not limited to Similac Sensitive, Total Comfort, NeoSure, Enfamil Nutramigen, and/or Gentlease (collectively the "**Products**"). Upon information and belief, Defendants' Products were prescribed/administered to and consumed by

infant Lizbeth Mejia and proximately caused her suffering and untimely death.

- 1.2 Plaintiff, Estela Mejia, is resident of Jefferson County, Texas and brings this lawsuit against Defendants individually and as Heir at Law of the Estate of Lizbeth Mejia. Tex. CIV. PRAC. & REM. CODE ANN. § 71.004; 71.021(b). Estela Mejia is a natural person and is Lizbeth Mejia's mother.
- 1.3 Plaintiff, Elvin Mejia, is resident of Jefferson County, Texas and brings this lawsuit against Defendants individually and as Heir at Law of the Estate of Lizbeth Mejia. Tex. CIV. PRAC. & REM. CODE ANN. § 71.004; 71.021(b). Elvin Mejia is a natural person and is Lizbeth Mejia's father.
- 1.4 Defendant, Abbott Laboratories, Inc. (hereinafter "Abbott"), is a corporation with its principal place of business in Illinois. Abbott's registered agent for service of process is CT Corporation System, 1999 Bryan St., Suite 1900, Dallas, TX 75201. Fed. R. Civ. P. 4(1). Abbott is a manufacturer of cow's milk—based infant feeding products and markets many of its products under the "Similac" brand name. Abbott manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty states, including Texas, infant cow's milk—based formula, including but not limited to Similac Sensitive, Total Comfort, and NeoSure. At all material times herein, Abbott solely or jointly designed, developed, manufactured, packaged, labeled, promoted, marketed, distributed, and/or sold Similac cow's milk—based products, including but not limited to Similac Sensitive,

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Total Comfortm and NeoSure. Thus, Abbott sells and has sold cow's milk—based medical products to Texas businesses and has purposefully availed itself of the privileges and benefits of conducting business in the State of Texas.

- 1.5 Defendant, Mead Johnson Nutrition Company, is a corporation incorporated under the laws of the State of Delaware with its principal place of business in Illinois. Mead Johnson Nutrition Company's registered agent for service of process is Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, TX 78701. Fed. R. Civ. P. 4(1).
- 1.6 Defendant, Mead Johnson & Company, LLC, is a limited liability company organized under the laws of the State of Delaware. Mead Johnson & Company, LLC's registered agent for service of process is Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, TX 78701. Fed. R. Civ. P. 4(1).
- Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC (hereinafter the "Mead Defendants") are manufacturers of milk–based infant feeding products and market many of these products under the "Enfamil" brand name. The Mead Defendants manufacture, design, formulate, prepare, test, provide instructions, market, label, package, sell, and/or place into the stream of commerce in all fifty states, including Texas, infant cow's milk–based formula, including but not limited to Enfamil Nutramigen and Gentlease. Thus, the Mead Defendants sell and have sold cow's milk–based medical products to Texas businesses and have purposefully availed themselves of the privileges and benefits of conducting business in the State of Texas.
 - 1.8 Mead Johnson Nutrition Company self-proclaims to be recognized as "a world

leader in pediatric nutrition" and traces its history back to the company's founding in 1905 by Edward Mead Johnson, Sr. It claims to be the "only global company focused primarily on infant and child nutrition" and that its "singular devotion has made our flagship 'Enfa' line the leading infant nutrition brand in the world." Boasting "more than 70 products in over 50 countries," it claims that its "products are trusted by millions of parents and healthcare professionals around the world." It is this very trust that the Mead Defendants have intentionally exploited for their own pecuniary gain at the expense of vulnerable families, like the Mejia family, throughout Texas, the United States, and the world.

II. STANDING & CAPACITY

- 2.1 Plaintiffs are the only living heirs of Lizbeth Mejia entitled to bring a wrongful death action under Texas Civil Practice & Remedies Code § 71.004(a). Due to her extremely young age (5 days old) at the time of her tragic death, Lizbeth Mejia did not acquire any assets (*i.e.*, separate property and/or community property) subject to estate distribution under Texas law. *See, e.g.*, Tex. ESTATE CODE ANN. § 201.001. Thus, a formal administration of Lizbeth Mejia's Estate is not necessary and no Texas court has appointed an estate administrator or executor. Nevertheless, in accordance with Texas Civil Practice & Remedies Code § 71.004(c), Plaintiffs hereby request that any future-appointed executor or administrator of Lizbeth Mejia's Estate **not bring and prosecute a wrongful death action** so that Plaintiffs may do so themselves in this lawsuit.
- 2.2 Furthermore, under Texas Civil Practice & Remedies Code § 71.021(b), Plaintiffs collectively bring a survival cause of action on behalf of the Estate of Lizbeth Mejia in their capacity as her heirs at law. *Shepherd v. Ledford*, 962 S.W.2d 28, 31–32 (Tex. 1998). Because Lizbeth Mejia possessed no assets subject to estate distribution prior to her death, **no**administration is pending and none is necessary in the future. *Id.* (holding that "[h]eirs at law *Mejia v. Abott Laboratories, Inc., et al.*Page 4 of 24 Plaintiffs' Original Complaint

can maintain a survival suit during the four-year period the law allows for instituting administration proceedings if they allege and prove that there is no administration pending is none is necessary."). Accordingly, Plaintiffs may bring this survival action under Texas law.

III. JURISDICTION & VENUE

- 3.1 Under 28 U.S.C. § 1332, this Court maintains original jurisdiction over this action as the matter in controversy exceeds \$75,000, exclusive of interest and costs, and Plaintiffs and Defendants are citizens of different states.
- 3.2 The Court has personal jurisdiction over the Defendants because Defendants are authorized to conduct and do conduct business in the State of Texas. More specifically, Defendants have sufficient minimum contacts with Texas and/or sufficiently avail themselves of the markets in this State through its promotion, sales, distribution, and marketing within this State to render the exercise of jurisdiction by the Court permissible. The Court also has personal jurisdiction over Defendants because they conduct business in Texas, purposely direct and/or directed their actions toward Texas, consent to being sued in Texas by registering an agent for service of process in Texas, and/or consensually submitted to the jurisdiction of Texas when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Texas necessary to constitutionally permit this Court to exercise personal jurisdiction. Moreover, Defendants' actions and/or inactions described herein were purposefully directed at and/or within the State of Texas, the damages sustained by Plaintiffs took place within the State of Texas, and the damages sustained by Plaintiffs were the result of Defendants' actions and/or inactions that were purposefully directed at and/or within the State of Texas.
- 3.3 Venue is proper in the Southern District of Texas, Galveston Division, pursuant to 28 U.S.C. §1391(b)(2) because a substantial part of the events or omissions giving rise to this Mejia v. Abott Laboratories, Inc., et al.

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claim occurred in Galveston County, Texas. Specifically, the wrongful death of Lizbeth Mejia.

IV. FACTUAL BACKGROUND

A. The Wrongful Death of Lizbeth Mejia

- 4.1 On May 13, 2020, Plaintiffs witnessed their daughter, Lizbeth Mejia, enter this world without complications as a healthy baby girl. For instance, Lizbeth's University of Texas Medical Branch—Galveston ("UTMP Galveston") records note that she was a "3 day old female with normal growth & development" born at 37 weeks. Due to a medical condition, Plaintiff Estela Mejia could not breastfeed her daughter. For this reason, upon information and belief, Lizbeth Mejia consumed infant formula(s) designed for babies born prematurely or "preterm."
- 4.2 On May 18, 2020, just five (5) days after Lizbeth Mejia's birth, the Mejia family faced a newborn parent's worst nightmare. Following her initial discharge from UTMP Galveston, Lizbeth Mejia experienced multiple poor feeding and vomiting episodes over the course of several days at Plaintiffs' home in Beaumont, Texas. Accordingly, on May 18, 2020, Plaintiffs transported Lizbeth to St. Elizabeth's Hospital in Beaumont for medical attention. After her arrival, Lizabeth experienced acute respiratory failure. Emergency medical services airlifted Lizbeth from St. Elizabeth's to UTMB Galveston's Pediatric Intensive Care Unit ("PICU"). During air transportation, Lizbeth sustained a cardiac arrest and arrived at UTMB Galveston with bloody secretions. Within minutes of being admitted to the PICU, Lizbeth experienced another cardiac arrest. Following forty (40) minutes of unsuccessful CPR, the attending physicians at UTMB Galveston pronounced Lizabeth Mejia dead around 9:00 PM on May 18, 2020.
- 4.3 A subsequent complete autopsy revealed that Lizbeth's cause of death was <u>diffuse</u>

 necrotizing enterocolitis. Upon information and belief, Lizabeth Mejia had consumed Similac cow–based formulas and/or Enfamil cow–based formulas designed, formulated, produced, and Mejia v. Abott Laboratories, Inc., et al.

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distributed by Defendants prior to her death. Stated differently, Lizbeth ingested the Products at issue in this lawsuit and, shortly thereafter, died from necrotizing enterocolitis ("NEC").

B. The Products and Resulting Necrotizing Enterocolitis

- 4.4 The protein ingredients most often found in Defendants' infant cow-based formulas are nonfat milk and whey protein concentrate from cow's milk. In recent years, there has been a growing scientific link between the use of cow's milk in infant formulas like Similac and Enfamil and an increased risk of NEC.
- 4.5 NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm babies. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30% of NEC-diagnosed infants die from the disease.
- 4.6 Symptoms associated with NEC include swelling, tenderness or hardness of the abdominal area, difficulty feeding, vomiting, diarrhea or constipation, green bile in the stomach, bloody bowel movements, fever or temperature changes, and low blood pressure or heart rate. NEC can result in serious injuries, including death.
- 4.7 Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems and death.
- 4.8 NEC causes the intestinal tissues to become inflamed, then perforated, which allows bacteria to leak into the abdomen or infiltrate the bloodstream. Once NEC develops, the

condition can progress rapidly from mild intolerance to fatal sepsis.

4.9 Nutrition for preterm babies is significantly important. Since the United States

ranks in the top ten countries in the world with the greatest number of preterm births, the market

of infant formula and fortifiers is particularly vibrant.

4.10 Originally, cow's milk-based products were believed to be good for the growth

of premature, low birth weight babies. However, science and research have advanced for decades

confirming the significant dangers of Defendants' cow's milk-based Products in causing NEC

and/or substantially contributing to NEC-related death in preterm and severely preterm, low-

weight infants, along with many other health complications and long-term risks to babies.

Nevertheless, Defendants did nothing to change the packaging, guidelines, instructions, and/or

warnings concerning the Products. Additionally, advances in science have created alternative

formulas and fortifiers that are derived from human milk and non-bovine based products; however,

the Defendants continue to promote and sell their obsolete Products.

4.11 As early as 1990, a prospective, multicenter study on 926 preterm infants found

that NEC was six (6) to ten (10) times more common in exclusively formula-fed babies than in

those fed breast milk alone and three (3) times more common than in those who received formula

plus breast milk. Babies born at more than thirty (30) weeks gestation confirmed that NEC was

rare in those whose diet included breast milk, but it was twenty (20) times more common in those

fed formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, Lancet.

336: 1519-1523 (1990).

4.12 In a study published in 2007, it was reported: "The use of an exclusive HUM

[Human] diet is associated with significant benefits for extremely premature infants <1259 g BW.

The benefits include decreased NEC rates, mortality, late-onset sepsis, PDA, BPD, ventilator days,

and ROP. Importantly, while evaluating the benefits of using an exclusive HUM-based protocol,

it appears that there were no feeding-related adverse outcomes. This study demonstrates that an

exclusive HUM diet provides important benefits beyond NEC." Hair, Amy, et al. Beyond

Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based

Diet. (Breastfeeding Medicine. 2016, Nov. 2, 11(2):70-75).

4.13 A study published in 2010 established that when premature babies were fed an

exclusive diet of mother's milk, donor milk, and human milk fortifier, these babies were 90% less

likely to develop surgical NEC. Sullivan, S., et al., An Exclusively Human Milk-Based Diet Is

Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine

Milk-Based Products. (Journal of Pediatrics. 2010; 156:562-7).

4.14 In 2011, the U.S. Surgeon General published a report titled, "The Surgeon

General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for

vulnerable premature infants, formula feeding is associated with higher rates of (NEC)." U.S.

Dept. of Health & Human Serv., Off. Of Surgeon Gen., "The Surgeon General's Call to Action to

Support Breast Feeding," p.1, (2011). This same report stated that premature infants who are not

breast fed are 138% more likely to develop NEC. *Id.*, Table 1, p.2.

4.15 In 2012, the American Academy of Pediatrics, an organization of 67,000

pediatricians, issued a policy statement that all premature infants should be fed an exclusive human

milk diet because of the risk of NEC associated with the consumption of cow's milk-based

products. The Academy stated that "[t]he potent benefits of human milk are such that all pre-term

infants should receive human milk ... If the mother's own milk is unavailable ... pasteurized donor

milk should be used." Breastfeeding and the Use of Human Milk, Pediatrics. 129:e827-e841

(2012).

4.16 A study published in 2013 showed that, all 104 premature infants participating in the study receiving an exclusive human-milk based diet, all 104 exceeded targeted growth standards, as well as length, weight, and head circumference gain. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet." A. Hair, et al., *Human milk Feed Supports Adequate Growth of Infants*≤1250 Grams Birthweight, BMC Research Notes. 6- 459(2013). Thus, inadequate growth was proven to be a poor excuse for feeding cow's milk-based products, but the practice continued largely due to extensive and aggressive marketing campaigns conducted by infant formula manufacturers like Defendants.

4.17 In another study published in 2013, it was reported: "This is the first randomized trial in EP [Extremely Premature] infants of exclusive HM [Human Milk] vs. PF [Preterm Formula]. The study found a significantly higher rate of surgical NEC in infants receiving the bovine preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU." Crisofalo, E.A., et al., *Exclusive Human Milk vs. Preterm Formula:* Randomized Trial in Extremely Preterm Infants. (J. Pediatr. 2013 Dec.; 163(6): 1592-1595).

- 4.18 In a study published in 2014, it was reported: "Necrotizing enterocolitis (NEC) is a devastating disease of premature infants and is associated with significant morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Good, Misty, et al., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*. (Expert Rev. Clin. Immunol. 2014 July; 10 (7): 875-884).
 - 4.19 In that same article, it was reported: "Necrotizing enterocolitis (NEC) is the most

frequent and lethal gastrointestinal disorder affecting preterm infants and is characterized by

intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death.

NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease

appears to be either stable or rising in several studies. The typical patient who develops NEC is a

premature infant who displays a rapid progression from mild feeding intolerance to systemic

sepsis, and up to 30% of infants will die from this disease."

4.20 In that same article, it was reported: "A wide variety of feeding practices exist on

how to feed the premature infant in the hopes of preventing necrotizing enterocolitis. There have

been several meta-analyses reviewing the timing of administration and rate of advancement of

enteral feedings in the premature infant as reviewed above, but there is no consensus on the precise

feeding strategy to prevent this disease. The exclusive use of human breast milk is recommended

for all premature infants and is associated with a significant decrease in the incidence of NEC. By

determining the specific ingredients in breast milk that are protective against NEC, it is our hope

that this devastating disease will one day be preventable."

4.21 In yet another study published in 2014, it was reported that an exclusive human

milk diet, devoid of Cow's Milk Products, was associated with "lower mortality and morbidity"

in extremely preterm infants without compromising growth and should be considered as an

approach to nutritional care of these infants. Steven Abrams, et al., Greater Mortality and

Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products.

(Breastfeeding Medicine. 9(6):281-286 (2014)).

4.22 In a study published in 2016, it was reported: "Extremely premature infants who

received an exclusive HUM diet had a significantly lower incidence of NEC and mortality. The

HUM group also had a reduction in late-onset sepsis, BPD, and ROP. This multicenter study

further emphasizes the many benefits of an exclusive HUM diet and demonstrates multiple improved outcomes after implementation of such a feeding protocol." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based*

Diet. (Breastfeeding Medicine. 2016, Nov. 2, 11(20:70-75.)

4.23 In a study published in 2017, it was reported: "Human milk is the preferred diet for preterm infants as it protects against a multitude of NICU challenges, specifically necrotizing enterocolitis. Infants who receive greater than 50% of mother's own milk (MOM) in the 2 weeks after birth have a significantly decreased risk of NEC. An additional factor in the recent declining rates of NEC is the increased utilization of donor human milk (DHM). This creates a bridge until MOM is readily available, thus decreasing the exposure to cow milk protein. Preterm infants are susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering the composition of bacterial flora. Ideally, preterm infants should be fed human milk and avoid bovine protein. A diet consisting of human milk-based human milk fortifier is one way to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a human milk diet." Maffei, Diana, Schanler, Richard J., *Human milk is the*

4.24 In another study published in 2017, it was reported: "in summary, HM [Human milk] has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two RCTs [Randomized Clinical Trials] on preterm infants weighing between 500 and 150 g at birth compared the effect of bovine milk—based preterm infant formula to MOM or DHM on the incidence of NEC. Both trials found that an exclusive HM diet results in a lower incidence

feeding strategy to prevent necrotizing enterocolitis! (Semin Perinatol. 2017 Feb; 41(1):36-40).

of NEC. A Cochrane systematic review that evaluated the effect of DHM or bovine milk-based

formula on health outcomes for preterm infants also determined that formula significantly

increases the risk of NEC." Shulhan, Jocelyn, et al., Current Knowledge of Necrotizing

Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products.

(ASN. Adv. Nutr. 2017; 8:8-0.91).

4.25 Yet another study that analyzed the data from a 12-center randomized trial

concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold

increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to

fortification with breast milk-based fortifier.

4.26 Another study conducted a randomized comparison of extremely preterm infants

who were given either (a) a diet of breast milk fortified with a breast milk fortifier or (b) a diet

containing variable amounts of cow's milk products. The babies given exclusively breast milk

products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17%

of the time.

4.27 Further, when Defendants recognized a shift in the medical community towards an

exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac

Human Milk Fortifier." Similar to the "Human Milk" formula, these names are misleading in that

they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-

based products. One study, for example, found that 91.2 percent of parents surveyed in the NICU

interpreted "human milk fortifier" as potentially meaning breast milk-based product.

C. Safer, Nutritionally Superior, Alternatives to the Products

4.28 A range of options are available that allow preterm and low-birth-weight infants

to be fed exclusively human-milk-based nutrition. For example, in addition to the mother's own

milk, an established network delivers pasteurized donor breast milk to hospitals nationwide.

Moreover, hospitals have access to shelf-stable formula and milk fortifiers derived from

pasteurized breast milk.

4.29 A diet based exclusively on breast milk and breast milk fortifiers provides all the

nutrition necessary to support premature and low-birth-weight infants without the elevated risk of

NEC associated with cow's milk-based products. For example, in a study analyzing preterm

infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104

infants exceeded standard growth targets and met length and head-circumference growth targets,

demonstrating that infants can achieve and mostly exceed targeted growth standards when

receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast

milk-based fortifiers to provide the additional nutritional supplements necessary for adequate

growth while receiving the protective benefits of a breast milk diet.

4.30 Defendants' Products not only pose a threat to infant health, but also displace the

breast milk they could otherwise receive. This displacement only increases infants' vulnerability

to NEC, as studies show that breast milk protects against the disease. For example, a study

analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based

diet is associated with significant benefits for extremely premature infants and that it produced no

feeding-related adverse outcomes.

4.31 For the above reasons, medical experts acknowledge that breast milk is the best

source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition

nourishes infants while creating significantly lower risk of NEC.

4.32 At the time infant Lizbeth Mejia was fed the Products, well–known scientific

research clearly demonstrated to Defendants that the Products cause and greatly increase the

likelihood that a baby will develop NEC, leading to severe injury and often death.

4.33 Despite the scientific consensus that Defendants' cow's milk-based Products

present a dire threat to the health and development of infants, Defendants have made no changes

to the Products or the Products' packaging, guidelines, instructions, or warnings. Instead,

Defendants have continued to sell their unreasonably dangerous Products to unsuspecting parents

and healthcare providers – generating huge profits as a result.

D. Misleading Marketing Facts

4.34 Abbott and the Mead Defendants have aggressively marketed their cow's

milk—based Products as medically endorsed and nutritionally equivalent alternatives to breast milk,

including prior to infant Lizbeth Mejia's birth.

4.35 Abbott and the Mead Defendants' marketing approach includes targeting the

parents of preterm infants while they are still in the hospital with messages that Defendants' cow's

milk-based Products are necessary for the growth and development of their vulnerable children.

Often these tactics implicitly discourage mother's from breastfeeding, which reduces the mother's

supply of breast milk. None of Defendants' marketing materials, including their promotional

websites, reference the science showing how significantly their Products increase the risk of NEC.

4.36 Defendants have designed powerful misleading marketing campaigns to deceive

parents into believing that: (1) cow's milk-based Products are safe, including for preterm infants;

(2) cow's milk-based Products are equal, or even superior, substitutes to breast milk; (3) cow's

milk-based Products are necessary for proper growth and development of preterm infants; and (4)

physicians consider Defendants' cow's milk-based Products a first choice. This marketing scheme

is employed despite Defendants knowing of and failing to warn of the extreme risk of developing

NEC and NEC-related death that cow's milk-based Products pose to infants like Lizbeth Mejia.

4.37 Despite strong medical and scientific evidence describing the dangers and risks that

cow's milk-based Products pose for both premature infants and infants generally, at all pertinent

times, Defendants have marketed their cow's-milk based Products, including their respective

Similar and Enfamil products, as a safe (and possibly better) alternative to breast milk.

4.38 Abbott's aggressive marketing for its Similac products included and still includes

targeting medical providers and parents of preterm infants with messages that Abbott's cow's

milk-based Products are necessary for the growth and development of their premature infants.

Indeed, it is believed that these marketing practices discourage some mothers from breastfeeding

altogether. All the while, Abbott's promotional websites have been and still are silent as to the

growing science that describes the risks that cow's milk-based Products, including its Similac

formulas, pose to premature infants and infants generally.

4.39 Abbott's misleading marketing campaign, which occurred during the time period

in question and through the present day, deceives medical providers and parents to believe that (1)

cow's milk-based Products are safe; (2) cow's milk-based Products are equal substitutes to human

breast milk; and (3) health care professionals prefer cow's milk-based Products to human breast

milk. Abbott has marketed its Products for premature infants as necessary for growth, and perfectly

safe for premature infants, despite knowing of the extreme risk of NEC and death.

4.40 Abbott's infant Products, including but not limited to Similac Sensitive, Total

Comfort and NeoSure, did not include labels that warned parents or healthcare providers of the

risks of developing NEC and/or dying from NEC.

4.41 The Mead Defendants specifically targeted medical providers and parents of

premature infants in their marketing. Numerous web-based advertisements use phrases such as

"Discover Your Baby's Trusted Formula with over 100 Years of Pediatric Nutrition

Experience" and "Enfamil: What a Baby Needs". Yet, searches on the Mead Defendants' websites

do not display any references to the risks of developing NEC or any reference to NEC at all.

4.42 The Mead Defendants' websites include several promises to mothers and their

premature infants, but have zero warning as to developing NEC or death resulting from NEC.

4.43 The Mead Defendants infant formulas, including but not limited to Enfamil

Nutramigen and Gentlease, did not include labels that warned parents or healthcare providers about

the risks of developing NEC following the consumption of their cow's milk-based Products.

4.44 The Mead Defendants misleading marketing campaign deceives medical providers

and parents to believe that (1) cow's milk-based Products are safe; (2) cow's milk-based Products

are equal substitutes to human breast milk; and (3) health care professionals prefer cow's milk-

based Products to human breast milk. The Mead Defendants have marketed its Products for

premature infants as necessary for growth, and perfectly safe for premature infants, despite knowing

of the extreme risk of developing NEC and death resulting from NEC.

4.45 Defendants' Products made from cow's milk, specifically for premature infants

such as Similac and Enfamil products, are unsafe to premature infants and infants generally and are

avoidable for use in that there is human donor milk available and/or human milk derived fortifier

products available made from human milk instead of cow's milk.

4.46 Despite knowing that their cow's milk-based Similac and Enfamil Products were

causing NEC, devastating injuries, and death in premature infants, Defendants did not recommend

to the FDA, hospital NICUs, or physicians that they should discuss the risks of NEC and NEC-

related death with the parents of a newborn.

4.47 There are human milk—based formulas and fortifier products which are feasible

alternatives to the subject Similac and Enfamil Products offered by the Defendants.

4.48 Prior to baby Lizbeth Mejia being fed Defendants' Similac and/or Enfamil cow's

milk-based Products, Plaintiffs were exposed to marketing for Defendants' Products, including

but not limited to Enfamil Nutramigen and Gentlease and Similac Sensitive, Total Comfort and

NeoSure. Defendants' marketing materials did not include labels that warned parents or healthcare

providers of the risks of NEC. Defendants' marketing also represented that these Products were

safe and necessary to the growth and nutrition of infants like Lizbeth Mejia.

4.49 Although Abbott promotes an aggressive marketing campaign designed to make

parents and healthcare providers believe that their Products are safe and necessary for growth of

an infant, the Products are in fact extremely dangerous for infants. Specifically, Abbott's Products

substantially increase the chances of an infant developing NEC and dying from NEC.

4.50 Although the Mead Defendants promote an aggressive marketing campaign

designed to make parents and healthcare providers believe that their Products are safe and

necessary for growth of a premature infant, the Products are in fact extremely dangerous for

infants. Specifically, the Mead Defendants' Products substantially increase the chances of an infant

developing NEC and dying from NEC.

4.51 Defendants' Products are commercially available at retail locations throughout the

State of Texas and online.

4.52 Despite knowing the risk of NEC associated with Defendants' Products for

infants, Defendants did not properly warn parents (including infant Lizbeth Majia's parents) of the

risk of developing NEC and/or dying from it.

4.53 Despite knowing the risk of developing NEC associated with Defendants'

Products for infants, Defendants did not warn doctors, hospitals, nurses, or medical staff

(including infant Lizbeth Mejia's healthcare providers) of the risk of developing NEC or dying

from it.

4.54 Defendants failed to properly warn parents (including infant Lizbeth Mejia's

parents) and medical providers (including infant Lizbeth Mejia's healthcare providers) that its

cow's milk-based Products can significantly increase the risk that an infant will develop NEC

and/or NEC-related death. Defendants failed to design said Products such as to make them safe,

and deceived the public, parents (including infant Lizbeth Mejia's parents), physicians, and

medical staff (including infant Lizbeth Mejia's healthcare providers) into believing that its

Products were a safe and necessary alternative, supplement, and/or substitute to human breast milk.

4.55 Despite knowing that its milk-based Products can significantly increase the risk

that an infant will develop NEC and/or NEC-related death, Defendants failed to require or

recommend that hospitals inform parents of the significant risks associated with feeding the

Products to infants like Lizbeth Mejia. After ingesting Defendants' Products, infant Lizbeth

Mejia's developed symptoms consistent with NEC, such as bloody stools and random vomiting,

which progressed and ultimately led to Lizbeth Mejia's death on May 18, 2020.

V. CAUSES OF ACTION

A. Products Liability: Design Defect

5.1 Defendants are "manufacturers" of cow's milk-based Products under Texas Civil

Practice & Remedies Code § 82.001(4).

5.2 At the time the cow's milk-based Products consumed by infant Lizbeth Mejia left

Defendants' possession, the Products' design was unreasonably dangerous in at least one or more of

the following ways:

i. The cow's milk-based Products significantly increased the risk that an infant will

develop NEC and/or NEC-related death; and

- ii. The cow's milk-based Products can directly cause an infant to develop NEC and/or NEC-related death.
- 5.3 At the time the cow's milk-based Products consumed by infant Lizbeth Mejia left Defendants' possession, safer alternative product designs existed. More specifically, baby formula that is human breast milk-based and contains breast milk fortifiers. This alternative product design provides all the nutrition necessary to support infants like Lizbeth Mejia without the significantly elevated risk of developing NEC and/or NEC-related death associated with Defendants' cow's milk-based Products. Additionally, at the time the cow's milk-based Products consumed by infant Lizbeth Mejia left Defendants' possession, baby formula that is human (i.e., donor) breast milk-based and contains breast milk fortifiers was both economically and technologically feasible.
- 5.4 For these reasons, the cow's milk-based Products were defectively designed and a proximate and producing cause of infant Lizbeth Mejia's development of NEC and resulting death. As such, Defendants are strictly liable for Plaintiffs' damages under Texas law. See TEX. CIV. PRAC. & REM. CODE ANN. § 82.005.

B. **Products Liability: Marketing Defect**

- 5.5 Defendants are "manufacturers" of cow's milk-based Products under Texas Civil Practice & Remedies Code § 82.001(4).
- 5.6 At the time the cow's milk-based Products consumed by infant Lizbeth Mejia left Defendants' possession, the Products contained marketing defects in the form of defective warnings and/or defective instructions that rendered the Products unreasonably dangerous as marketed in at least one or more of the following ways:
- i. Defective warning labels and/or instruction on the cow's milk-based Products that failed to warn healthcare providers and parents like Plaintiffs of the significantly increased risk that an infant will develop NEC and/or NEC-related death after Mejia v. Abott Laboratories, Inc., et al.

consuming the Defendants' Products; and

ii. Defective warning labels and/or instructions on the cow's milk-based Products that failed to warn healthcare providers and parents like Plaintiffs that an infant may develop NEC and/or NEC-related death as a direct result of consuming the

Defendants' Products.

5.7 At the time the cow's milk-based Products consumed by infant Lizbeth Mejia left

Defendants' possession, the defective warnings and instructions failed to warn of dangers known

to Defendants concerning the consumption of Products and the risk that an infant will develop

NEC and/or NEC-related death. These defective warnings and instructions are a proximate and

producing cause of infant Lizbeth Mejia's development of NEC and resulting death. See Lee Lewis

Const., Inc. v. Harrison, 70 S.W.3d 778, 784 (Tex. 2001) (under Texas law "[m]ore than one act

may be the proximate cause of the same injury.").

C. Gross Negligence

5.8 At the time the cow's milk-based Products consumed by infant Lizbeth Mejia left

Defendants' possession, the consumption of these Products involved an extreme degree of risk that

infants like Lizbeth Mejia will develop NEC and/or NEC-related death. At this time, Defendants

had actual, subjective awareness that an infant's consumption of their cow's milk-based Products

involved an extreme risk that the baby will develop NEC and/or NEC-related death. Thus, by

failing to warn healthcare providers and parents like Plaintiffs of this extreme risk, Defendants

displayed a conscious indifference to the rights, safety, and welfare of infants like Lizbeth Mejia.

5.1 This behavior constitutes gross negligence under Texas law. TEX. CIV. PRAC. &

REM. CODE ANN. § 41.001(11). Because Defendants' gross negligence was a proximate cause of

infant Lizbeth Mejia's development of NEC and resulting death, Plaintiffs are entitled to recover

exemplary damages against Defendants. See Lee Lewis Const., Inc., 70 S.W.3d at 784.

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VI. DAMAGES

A. Estela Mejia – Individually

- **6.1** Plaintiff Estela Majia would show that, as a direct and proximate result of the death of her newborn daughter, Lizbeth Mejia, she sustained the following wrongful death damages:
 - i. Pecuniary loss sustained in the past;
 - ii. Pecuniary loss that, in reasonable probability, will be sustained in the future;
 - iii. Loss of companionship and society sustained in the past;
 - iv. Loss of companionship and society that, in reasonable probability, will be sustained in the future;
 - v. Mental anguish sustained in the past; and
 - vi. Mental anguish that, in reasonable probability, will be sustained in the future;
- 6.2 Plaintiff Estela Mejia would also show that, because Lizbeth Mejia died as a direct and proximate result of Defendants' gross negligence, she (as Lizbeth Mejia's mother) is entitled to recover exemplary damages from Defendants. *See Lee Lewis Const., Inc.*, 70 S.W.3d at 784; TEX. CIV. PRAC. & REM. CODE ANN. § 71.009.

B. Elvin Mejia – Individually

- **6.3** Plaintiff Elvin Majia would show that, as a direct and proximate result of the death of his newborn daughter, Lizbeth Mejia, he sustained the following wrongful death damages:
 - i. Pecuniary loss sustained in the past;
 - ii. Pecuniary loss that, in reasonable probability, will be sustained in the future;
 - iii. Loss of companionship and society sustained in the past;
 - iv. Loss of companionship and society that, in reasonable probability, will be sustained in the future;
 - v. Mental anguish sustained in the past; and

vi. Mental anguish that, in reasonable probability, will be sustained in the future;

6.4 Plaintiff Elvin Majia would also show that, because Lizbeth Mejia died as a direct and proximate result of Defendants' gross negligence, he (as Lizbeth Mejia's father) is entitled to recover

exemplary damages from Defendants. See id.

C. Estela Mejia and Elvin Mejia – Heirs at Law of the Estate of Lizbeth Mejia

6.5 Plaintiffs Estela Mejia and Elvin Mejia, as Heirs at Law of the Estate of Lizbeth Mejia,

would show that, as a direct and proximate result of Lizbeth Mejia's development of NEC, Lizbeth

accrued the following survival damages from her contraction of NEC until her tragic death:

i. Pain and mental anguish;

ii. Medical expenses; and

iii. Funeral and burial expenses.

6.6 Plaintiffs would also show that, because Lizbeth Mejia died as a direct and proximate

result of Defendants' gross negligence, Plaintiffs are entitled to recover exemplary damages on behalf

of Lizbeth Mejia's Estate from Defendants. See Lee Lewis Const., Inc., 70 S.W.3d at 784; Hofer v.

Lavender, 679 S.W.2d 470,475 (Tex. 1984).

VII. <u>JURY TRIAL DEMAND & PRAYER</u>

7.1 Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs demand a jury trial and have

tendered the appropriate fee.

7.2 Plaintiffs hereby request that Defendants be cited to appear and answer and that, on

final hearing, Plaintiffs obtain judgment against Defendants for an amount within the jurisdictional

limits of this Court, together with pre-judgment and post-judgment interest as provided by law,

costs of court, and for such other and further relief, at law or in equity, to which Plaintiffs are justly

entitled.

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Respectfully Submitted,

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